

# Notice of Allowability

Application No.

09/857,308

Examiner

Christopher H. Yaen

Applicant(s)

ITOH ET AL.

Art Unit

1642

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/4/2005.
2. ☒ The allowed claim(s) is/are 9-12,16,17,19,20,28 and 29.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Christopher Yaen  
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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Gallagher on 6/21/2005.

The application has been amended as follows:

1-8. (cancelled).

9. (previously presented) An isolated tumor antigen peptide consisting of 8 to 14 amino acids that is a fragment of the amino acid sequence of SEQ ID NO: 1 and that binds to an HLA antigen and is recognized by cytotoxic T lymphocytes.

10. (previously presented) The isolated tumor antigen peptide consisting of 8 to 14 amino acids of claim 9 wherein the HLA antigen is HLA-A24.

11. (currently amended) An isolated tumor antigen peptide consisting of 8 to 14 amino acids that is a fragment of the amino acid sequence of SEQ ID NO: 1, which fragment comprises a sequence selected from an amino acid sequence shown in any one of SEQ ID NOs: 3-18, or an isolated tumor antigen peptide consisting of 8 to 14 amino acids that is a fragment of the amino acid sequence of SEQ ID NO: 1, which

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comprises a sequence selected from an amino acid sequence shown in any one of SEQ ID NOs: 3-18 wherein the amino acid residue at position 2 is substituted by tyrosine, phenylalanine, methionine, or tryptophan, and/or the C-terminus is substituted by phenylalanine, leucine, isoleucine, tryptophan, or methionine, and which binds to an HLA antigen and is recognized by cytotoxic T lymphocytes.

12. (currently amended) The isolated tumor antigen peptide consisting of 8 to 14 amino acids of claim 11, which comprises a sequence selected from an amino acid sequence shown in any one of SEQ ID NOs: 3-5, or an isolated tumor antigen peptide consisting of 8 to 14 amino acids which comprises a sequence selected from an amino acid sequence shown in any one of SEQ ID NOs: 3-5 wherein the amino acid residue at position 2 is substituted by tyrosine, phenylalanine, methionine, or tryptophan, and/or the C-terminus is substituted by phenylalanine, leucine, isoleucine, tryptophan, or methionine, and which has the ~~functionally equivalent~~ cytotoxic T lymphocyte binding properties of a peptide ~~having the sequence~~ consisting of SEQ ID NO: 3, 4, or 5.

13. - 15. (cancelled).

16. (previously amended) The isolated tumor antigen peptide consisting of 8 to 14 amino acids of claim 12, which comprises a sequence selected from an amino acid sequence shown in any one of SEQ ID NOs: 19-21.

17. (previously presented) A composition, which comprises as an active ingredient at least one substance selected from the isolated tumor antigen peptides consisting of 8 to 14 amino acids according to any one of claims 9 to 12, and 16.

18. (cancelled).

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19. (previously presented) A recombinant polypeptide obtainable by expressing a recombinant DNA comprising at least one of DNAs that encode the tumor antigen peptides consisting of 8 to 14 aminoacids according to any one of claims 9 to 12, and 16.

20. (previously presented) A composition, which comprises as an active ingredient the recombinant polypeptide of claim 19.

21.-27. (cancelled).

28. (currently amended) A diagnostic agent for tumors, which comprises the tumor antigen peptide consisting of 8 to 14 amino acids according to any one of claims 9 to 12, and 16[.], ~~or an isolated protein that is encoded by a DNA any one the following (a) to (d):~~

~~(a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO:1~~

~~(b) a DNA comprising the nucleotide sequence of SEQ ID NO:2,~~

~~(c) a foreign DNA carried in E. coli JM109 (3D9) (deposit number FERM 8P-6929), and~~

~~(d) a DNA which hybridizes with a DNA of any one of (a) to (c) under stringent hybridization conditions wherein said DNA encodes a tumor antigen protein which gives rise to tumor antigen peptide(s) that binds to an HLA antigen and are recognized by cytotoxic T lymphocytes.~~

29. (previously presented) A diagnostic agent for tumors, which comprises the recombinant polypeptide of claim 19.


**All rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 4/4/2005.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
June 27, 2005

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**  
6/27/05